

K 002103

NOV - 2 2000

SIMPLICITY™ Spinal System
Summary of Safety and Effectiveness
October 2000

- I. **Company:** **Medtronic Sofamor Danek USA**
 1800 Pyramid Place
 Memphis, TN 38132
 (901) 396-3133
- II. **Proposed Proprietary Trade Name: SIMPLICITY™ Spinal System**
- III. **Product Description**

The SIMPLICITY™ Spinal System consists of a variety of rods, hooks, screws and CROSSLINK® plate components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The implant components of the SIMPLICITY™ Spinal System are fabricated from medical grade stainless steel described by ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2.

Certain implant components from other Medtronic Sofamor Danek spinal systems can be used with the SIMPLICITY™ Spinal System, specifically TSRH® and CD HORIZON® CROSSLINK® plates.

SIMPLICITY™ hooks are intended for posterior use only.

The purpose of this 510(k) submission is to file an initial premarket application for the SIMPLICITY™ Spinal System.

IV. Indications

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the SIMPLICITY™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the SIMPLICITY™ Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the SIMPLICITY™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc

confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as a unilateral anterolateral thoracic/lumbar system, the SIMPLICITY™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

V. Substantial Equivalence

Documentation was provided which demonstrated the SIMPLICITY™ Spinal System to be substantially equivalent to the previously cleared CD HORIZON® Spinal System and the Silhouette Spinal System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2000

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K002103
Trade Name: Simplicity Spinal System
Regulatory Class: Class II
Product Code: KWP, MNH, MNI, KWQ
Dated: October 4, 2000
Received: October 6, 2000

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

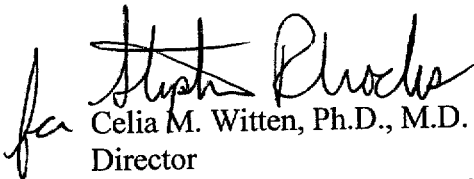
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Richard W. Treharne, Ph.D.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002103

Device Name: SIMPLICITY™ Spinal System

Indications for Use:

The SIMPLICITY™ Spinal System is intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the SIMPLICITY™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

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When used as a unilateral anterolateral thoracic/lumbar system, the SIMPLICITY® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRL Office of Evaluation (ODE)

Steph Plurke
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K002103

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-counter Use _____

(Optional 1-2-96)